DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on 06/17/2011. As directed by the amendment: claims 1 and 42 have been amended, claims 2, 4-20, 28-30, 32-41, 43 and 49-51 have been cancelled, and no new claims have been added. Thus, claims 1, 3, 21-27, 31, 42, 44-48 and 52-54 are presently pending in this application.

Response to Arguments

2. Applicant's arguments, see page 3, filed 06/17/2011, with respect to clams 1 and 33 have been fully considered and are persuasive. The rejection under 35 112 first paragraph of claims 1 and 42 has been withdrawn.

3. Applicant's arguments with respect to claims 1 and 42 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 3, 21-27, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (20040030391) in further view of Ferree (PG Pub no. 20030204260).

6. Regarding claim 1, Ferree '0391 substantially disclosed all the elements of the claims including a two-part prosthetic spinal nucleus device (figure 9A) replacing a nucleus of a spinal disc and being implanted in an intervertebral space within a natural intact annulus and between natural intact end plates attached to adjacent axially spaced upper and lower vertebral bones (figure 9D), the device comprising: a rigid upper shell (component; paragraph 49) having a one-piece elongate body having a predetermined length between opposite narrow ends and a predetermined width between opposite elongate sides and including a smooth outer surface having a flat configuration (via axial loads, paragraph 43) for facing and non-invasively contacting the natural end plate of the upper vertebra for sliding engagement therewith (free to self center, paragraph 39) and sized to fit within the natural annulus of the spinal disc (closely matches the concavities of disc; paragraph 40) a rigid lower shell (component; paragraph 49) having a one-piece elongate body having a predetermined length between opposite narrow ends and a predetermined width between opposite elongate sides and including a smooth outer surface having a flat configuration (via axial load, paragraph 43) for facing and non-invasively contacting the natural end plate of the lower vertebra for sliding engagement therewith (free to self center, paragraph 39) and sized to fit within the natural annulus of the spinal disc (closely matches the concavities of disc (paragraph 40); inner, arcuate bearing surfaces of the one-piece bodies of the upper and lower shells that generally face are in engagement with each other (components articulate with each other, paragraph 49) each other each extending substantially entirely across the width of the respective shell bodies to the opposite sides thereof (see figure 9A) see

such that the inner, arcuate bearing surfaces have the widthwise size thereof maximized for distributing loading exerted by the adjacent vertebrae across substantially the entire width of the respective shell bodies; and the elongate sides of each of the shell bodies extending lengthwise between the narrow ends thereof so that the sides are longer than the width across narrow ends (oval shaped; paragraph 47; figure 4b) to allow the shells to be arranged with narrow ends of the shells shell bodies leading the shells as the shells are inserted through an incision smaller than the elongated sides of the shells shell bodies so that the natural annulus retains the shells in the intervertebral space with the smooth outer surfaces of the shell bodies extending continuously without interruption across the entire extent thereof between the ends and sides of the respective shell bodies (outer surface polished for articulation; paragraph 41) **except** for a rigid upper shell and rigid lower shell having a smooth outer surface having a flat configuration extending substantially entirely across the length and width of the shell.

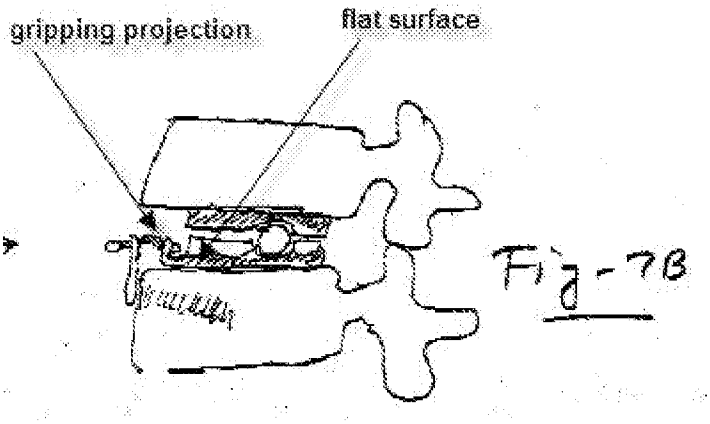
Ferree '0391 teaches a rigid upper shell and rigid lower shell having a smooth outer surface having a flat configuration extending substantially entirely across the length and width of the shell as shown in figure 9. It would have been obvious to one of ordinary skill in the art at the time of the invention to include such surfaces for the purpose of allowing freedom of motion in all directions (c4:L53-56).

7. Regarding claim 3, Ferree disclosed wherein the shell bodies are configured to be sequentially inserted through the incision in the annulus, and be assembled within the annulus (via two distinct spacer components; paragraph 49).

8. Regarding claim 21-23, Ferree disclosed all the elements of the claim except for at least one of the shells includes a gripping projection integral with the body of the one shell configured to allow a separate tool to grip around the projection for tool insertion of the shells through the annulus incision into the intervertebral space and shifting of the shells therein so that the narrow shell ends are not aligned with an insertion direction of the shells through the incision.

Ferree (PG Pub no. 20030204260) teaches shells (intradiscal device; figure 7B) that includes a gripping projection (see annotated figure 7B) integral with the body of the one shell configured to allow a separate tool to grip around the projection for tool insertion of the shells through the annulus incision into the invertebral space and shifting of the shells (controlled range of motion (paragraph 41) wherein the gripping projection comprises a gripping post of the at least one of the upper and lower shells that projects from the one shell toward the other of the upper and lower shells (see annotated figure 9) and wherein the gripping projection includes an arcuate engagement surface for rotating the one shell with the tool (via swivel feature; paragraph 42, figure 6) and a generally flat abutment surface (via anterior portion; paragraph 43) for locking the one shell against rotation with the tool. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the grip projection with an arcuate engagement surface and flat abutment surface for the purpose of providing an intradiscal device with the ability to self center while remaining safely inside the annulus

(paragraph 14).



9. Regarding claim 24, Ferree disclosed engaging concave and convex bearing surfaces of the upper and lower shell bodies that bear against each other for substantially the entire arcuate extent thereof without discontinuities in the bearing surfaces (see figure 9a).

10. Regarding claim 25, Ferree disclosed wherein shell bodies include flat surface portions (inferior surface flat; paragraph 51) adjacent the concave and convex bearing surfaces portions.

11. Regarding claim 26, Ferree teaches wherein the flat surface portion of one of the shell bodies includes an integral gripping post projecting away therefrom (see annotated figure 7B).

12. Regarding claim 27, Ferree disclosed wherein one of the shell bodies includes a flat surface portion and the inner bearing surface of the one shell body is a concave surface portion recessed from the flat surface portion, and the other shell body includes a flat surface portion and the inner bearing surface of the other shell body is a dome.

13. Regarding claim 52, Ferree disclosed wherein the outer bearing surfaces are substantially race track shaped (oval shaped; paragraph 47; figure 4b) for allowing the bearing members to fit within the natural annulus.

14. Regarding claim 53, Ferree disclosed wherein the narrow ends of the shells each have an arcuate configuration mad the elongate sides extend parallel to one another between the narrow ends (see figure 4B).

15. Regarding claim 54, Ferree disclosed wherein the smooth outer surfaces of the shells are entirely free of bone-engaging protrusions or surface roughening (via polishing; paragraph 41) to promote sliding engagement of the bearing members with the end plates such that the nucleus device is allowed to move freely along the endplates within the annulus.

16. Claims 31, 42, 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (20040030391) and alternately Ferree (20040030391) in further view of Casutt (PG Pub no. 20030045939).

17. Regarding claims 31 and 48, Ferree disclosed all the elements of the claim including the members constructed from polymer (paragraph 9) except for wherein the bodies of the rigid upper shell and the rigid lower shell are entirely of a polyetheretherketone (PEEK) material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the polymer of PEEK for the purpose of providing a biologically acceptable material with elastic or spring like properties (paragraph 9), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the

intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Additionally, Casutt teaches endplates that are made from PEEK (paragraph 29). Therefore it would have been obvious to one of ordinary skill I the art at the time of the rejection to include the PEEK of Casutt for the purpose of providing a high performance polymer.

18. Regarding claim 42 and 44, see claims 1 and 31.

19. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (20040030391) in further view of Ferree (PG Pub no. 20030204260) and alternatively Ferree (20040030391) in further view of Ferree (PG Pub no. 20030204260) in further view of Casutt (PG Pub no. 20030045939).

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA LEVINE whose telephone number is (571)270-5413. The examiner can normally be reached on Monday-Thursday 7:30am-5:00pm ETA.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. L./
Examiner, Art Unit 3774

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774